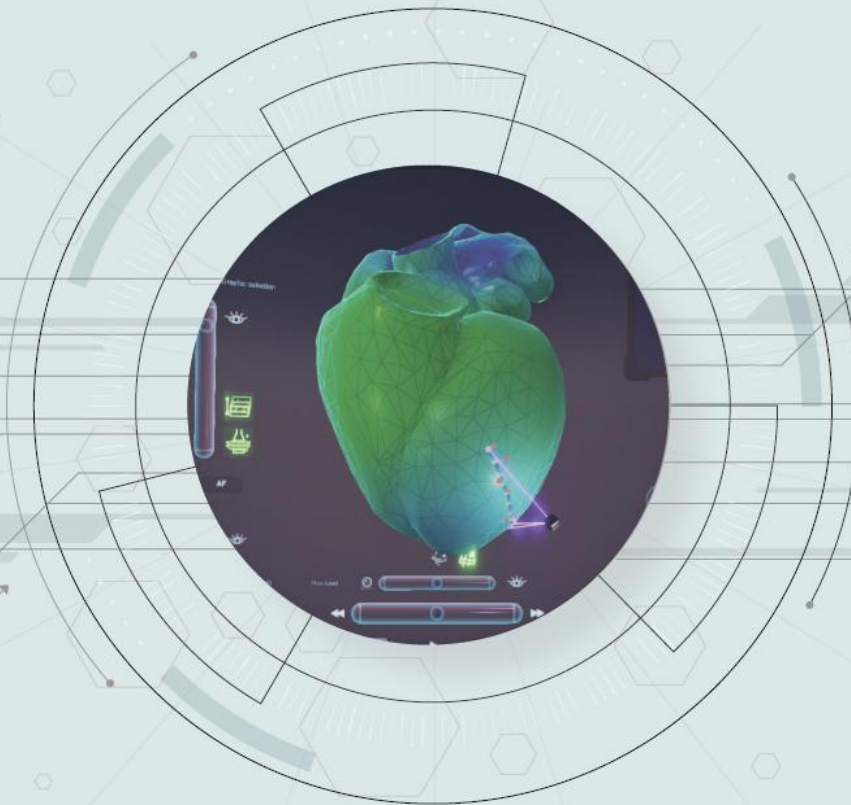




CARDIOTM

INSTRUCTIONS FOR USE



SOFTWARE VERSION

1.0.0



PLEASE READ THIS DOCUMENT CAREFULLY BEFORE USING VR-CARDIO

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Trademarks

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*PATENT NOTICE: This system is covered by the following patent register: European Patent Office.
No. 23 382 800.3*

List of acronyms

Abbreviation	Meaning
A/D	Analog to digital
AF	Atrial Fibrillation
API	Application Programming Interface
AR	Augmented Reality
AEMPS	Spanish Agency of Medicines and Medical Devices
CPU	Central Processing Unit
DICOM	Digital Imaging and Communications in Medicine
ECG	Electrocardiogram
ECGi	Electrocardiographic imaging
EP	Electrophysiology
FZM	Fibrillation Zones Map
FPS	Frames Per Second
GPU	Graphics Processing Unit
GUI	Graphical User Interface
ID	Identity
PC	Personal Computer
VR	Virtual Reality

1. Introduction

VR-CARDIO is an advanced clinical software system designed to assist electrophysiologists and cardiology specialists. This medical device provides detailed and accurate visualization of the heart's electrical activity, supporting accurate cardiac behaviour knowledge and more effective patient care. It offers an immersive, three-dimensional stereoscopic view of the heart's electrical activity, enhancing non-invasive mapping capabilities during the evaluation of conditions such as Atrial Fibrillation and other arrhythmias.

The software supports the processing, visualization, analysis, and interpretation of cardiac electrophysiological data, aiding in the understanding of arrhythmias and guiding preliminary assessments. It helps identify the origin of arrhythmias to assist in diagnosis and targeted treatment planning. VR-CARDIO complements traditional diagnostic methods, offering advanced visualization tools to deepen clinical insights into arrhythmia mechanisms and improve the effectiveness of non-invasive cardiac care. Its ability to deliver three-dimensional and holographic visualizations overcomes the limitations of two-dimensional systems.

VR-CARDIO operates as part of a broader clinical process, leveraging data collected by external acquisition systems which capture signals from multiple points on the torso in a non-invasive manner. Through the Inverse Problem solution and mathematical algorithms VR-CARDIO infers the electrical signals of the heart from the measured body surface signals, producing accurate and non-invasive visual maps of the heart's electrical activity. The visualization method is patented under European Patent EP23382800.3.

The user will find detailed information on the technical specifications of the system, operating instructions, safety protocols, methods for accurate data interpretation and practical examples. IFU is not only an essential tool to take full advantage of VR-CARDIO's innovative capabilities but also ensures compliance with the regulations established by the Spanish Agency of Medicines and Medical Devices (AEMPS). VR-CARDIO is aimed at cardiologists, electrophysiology technicians and other professionals in the sector, and this document is key to effectively use and implement VR-CARDIO, thereby improving the efficiency of cardiac care procedures and raising the standard of care for patients.

1.1 Intended use

VR-CARDIO family is intended for use by electrophysiologists and cardiology specialists outside the operating room as an aid to visualization and interpretation of three-dimensional electro anatomical maps of cardiac electrophysiology. It provides an immersive, three-dimensional stereoscopic view of the electrical behaviour of the heart, enhancing non-invasive mapping capabilities during the evaluation of conditions such as atrial fibrillation and other arrhythmias.

The software enables the analysis, visualization and informative interpretation of cardiac electrophysiological data, aiding in the understanding of complex arrhythmias and guiding preliminary assessments. It is beneficial in assisting patients at risk of cardiac arrhythmias or who are being evaluated for them.

Its use is intended to assist traditional diagnostic methods and to deepen the understanding of arrhythmia mechanisms in order to develop non-invasive management strategies.

The VR-CARDIO family consists of two main components:

- VR-CARDIO Explore (Ref. VR-CARDIO-01) is a web page that receives the raw data, stores it, launches the algorithms to process the data and uploads it to the database so that the VR-CARDIO VHET360 can access it.
- VR-CARDIO VHET360 (Ref. VR-CARDIO-02) is a software system designed for the visualization and interpretation of three-dimensional electroanatomical maps of cardiac electrophysiology. It assists cardiology specialists in evaluating and treating arrhythmias such as atrial fibrillation.

2. Symbols and indications

2.1 Symbols

	Warning: this symbol is used to warn the user of a potential hazard related to the use of the software that could have consequences for the safety of the patient or the user.
	Caution: this symbol is used to indicate that caution is necessary when using the software, without consequence to patient or user safety.
	Consult instructions for use or consult electronic instructions for use.
	Name of manufacturer: YYYY-MM-DD corresponds to date of manufacture
	Software reference: indicates the manufacturer's batch code in order to identify a specific medical device.
	Software serial number

	Medical Device
	Unique Device Identifier
	Caution: Federal (US) law Part 21 CFR 801 Subpart D restricts this device to sale by or on the order of a physician, only under prescription.

2.2 User profile characterization

VR-CARDIO is intended for use by electrophysiologists and cardiology specialists outside of operating room settings. Usage typically occurs during patient consultations or follow-up visits, where detailed cardiac data are required to support informed clinical decision-making.

VR-CARDIO is specifically designed for integration into various non-surgical areas within hospital environments.

2.3 Patient population characterization

VR-CARDIO is intended for use on individuals aged 18 or older, who are undergoing electrophysiological (EP) procedures.

3. Warnings

The use of VR-CARDIO medical device includes various types of warnings, as follows:

3.1 VR-CARDIO Explore warnings

	All users must be trained before using the device.
---	--

	Please read this IFU carefully and keep it for future reference.
	Inappropriate use of external data collection systems may result in poor data acquisition.
	A noticeable loss of performance may occur if the computer where the software runs lacks high GPU processing power.
	Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.
	Incorrect patient registration or data acquisition may lead to inaccurate results.
	Internet connection loss may result in data loss.

3.3 VR-CARDIO VHET 360 warnings

	All users must be trained before using the device.
	Please read this IFU carefully and keep it for future reference.
	Any modification to the system will require a safety and performance reassessment.
	Inappropriate use of external data collection systems may result in poor data acquisition.
	A noticeable loss of performance may occur if the computer where the software runs lacks high GPU processing power.

	Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.
	Incorrect patient registration or data acquisition may lead to inaccurate results.
	Internet connection loss may result in data loss.
	A poor internet connection may make the Cloud cases downloading unavailable.
	The images belong to real hearts, but the layout and resolution of the screen may affect the real size proportion.
	VR glasses and a compatible PC are required for VR visualization.
	The medical professional who creates a virtual room is responsible for the individuals with whom the room joining code is shared, since personal data will be shared with third parties.
	The algorithm may generate information suggestive of an arrhythmia, offering support for clinical assessment; however, it is not intended to replace a medical diagnosis. If the system indicates a potential arrhythmia, the finding must be reviewed and confirmed by a qualified healthcare professional using the tools provided by VR-CARDIO VHET360.
	The presented maps and heart reconstructions serve as clinical assessment support tools and should not be interpreted in isolation. They do not replace the medical judgment of trained professionals in any case.
	The filters used are the same as the ones used in VR-CARDIO Explore. A misplacement of this data will influence the filtering quality of the data in VR-CARDIO VHET360.
	Poor data acquisition may cause the display of the panels to differ from reality.

4. Technical characteristics

4.1 Minimum requirements for VR-CARDIO VHET360

4.1.1 Minimum screen resolution

Display resolution and aspect ratio: Minimum Full HD (1080p) resolution. Only landscape orientation is supported. Aspect ratios supported: 16:9. Mobile devices are not supported. Minimum resolution 1920x1080.

4.1.2 Minimum network requirements

Each streaming device requires a stable throughput of at least 8 Mbps.

In the medical center, for shared sessions, a stable throughput of 12 Mbps must be provisioned for every three devices accessed simultaneously.

4.1.3 Minimum computer requirements

Quantity	1
Connection	To be connected to one of the network points
Memory	8 GB or more
Disk Space	Minimum of 2GB free space
CPU	Intel Core i7-1260P 2.1 GHz (16 CPU)
GPU	NVIDIA T550 Mobile GDDR6 4 GB
Required infrastructure	Network point or private Wi-Fi
Operating system	Windows 10 or higher - 64Bits
Installed applications	A web browser and VR-CARDIO VHET360

4.1.4 Minimum VR or holographic computer requirements

Quantity	1
Connection	To be connected to one of the network points

Memory	8 GB or more
Disk Space	Minimum of 2GB free space
CPU	Intel Core i7-1260P 2.1 GHz (16 CPU)
GPU	NVIDIA T550 Mobile GDDR6 4 GB
Required infrastructure	nd network point or private Wi-Fi
Operating system	Windows 10 or higher - 64Bits
Installed applications	A web browser and VR-CARDIO VHET360

4.1.5 Virtual reality device

- **Option 1 Viewfinder Model: HP Reverb Professional Edition VR 1000**
 - Connection type: USB A and Mini DisplayPort
 - Software: Windows Mixed Reality
- **Option 2 Viewer model: Meta Quest 2**
 - Connection type: USB C to A
 - Software: Oculus Meta Quest Link

4.1.6 Holographic display

- **Hologram model: Mirror portrait**
 - Connection type: USB C and HDMI.
 - Software: Looking Glass Bridge

4.2 IT-security measures

4.2.1 Access to VR-CARDIO

- To prevent unauthorized access, login with registered credentials is required.
- Users must create strong passwords.
- In case of authentication failures, use the password reset function or contact technical support.

4.2.2 Data protection

- All patient data is encrypted during transmission and storage.
- User consent must be obtained before processing patient data.
- To prevent unauthorized data sharing, audit logs track all access and modifications.

4.2.3 Session security

- Sessions are secured with dynamic tokens that change periodically to prevent interception.
- Dynamic security tokens refresh every 5 minutes to prevent interception.
- Even if data is intercepted, it remains in a proprietary format and is unreadable without decryption keys.

4.2.4 Session security

- Patient data cannot be lost; all records are stored in a redundant database with daily backups.
- For critical data (e.g., ECG signals), the system validates file integrity before processing.

4.2.5 System update

- Install all software updates promptly to ensure security and performance. Notifications will appear when updates are available.
- Unauthorized software is blocked; only approved versions can interact with VR-CARDIO.

4.3 Usability measures

4.3.1 Image and signal accuracy

- Images and signals are diagnostic aids only. Clinicians must correlate outputs with clinical findings.
- Poor resolution/noisy signals may indicate improper external input data. Discontinue use and contact support if anomalies persist.

4.3.2 Data uploads

- Ensure stable internet connectivity during uploads. The system will display confirmation upon success.

4.3.3 Troubleshooting

- Authentication Issues: Use password reset or contact support.
- Session Errors: Restart the application and log in again. Persistent errors must be reported.

5. Accessories

For optimal performance and compatibility with the holographic display and VR applications, several accessories are recommended, where the device has been fully tested.

Please find below a list of recommended accessories. The use of any accessories not included in this list is the user's responsibility.

- HP Reverb Professional Edition VR 1000 viewfinder, which connects via USB A and Mini DisplayPort and uses Windows Mixed Reality software.
- Meta Quest 2 viewer, which connects through a USB C to A cable and operates with Oculus Meta Quest Link software.
- To enhance the holographic display experience, the Mirror Portrait hologram model is the recommended one. It requires a connection via USB C and HDMI and utilizes Looking Glass Bridge software.
- A computer that fulfils the minimum requirements specified above is also required.

6. Device Description

VR-CARDIO is an advanced system designed to help in the detection and analysis of cardiac arrhythmias. This medical software provides detailed and accurate visualization of the heart's electrical activity, helping doctors make an accurate diagnosis and more effective treatment planning. It is intended for use by a cardiac signal specialist, as electrophysiologists and cardiology specialists may be.

Specific clinical applications include:

- I. **Electro-anatomical mapping and advanced visualization of electrical signals:** through the external electrical signals collected from the subject's torso, VR-CARDIO can perform an electro-anatomical reconstruction of the heart. Thanks to its three-dimensional (3D), holographic, stereoscopic 360° visualization of a model of the patient's cardiac geometry and temporal activation maps. This advanced visualization provides the clinician with a deeper understanding of the patient's cardiac conditions and facilitates clinical decision-making.
- II. **Help in Arrhythmia detection:** VR-CARDIO is specifically designed to help in the identification of different types of cardiac arrhythmias. From signals recorded at multiple points on the patient's torso, the device shows electrical signals from the heart, allowing a detailed analysis of the heart activity. VR-CARDIO provides information on the mechanistic basis of arrhythmias, whose objective is to help in the diagnosis and targeted treatment planning.
- III. **Complementing conventional cardiac navigation systems:** VR-CARDIO stands out for its advanced visualization, offering a significant complement to conventional cardiac navigation systems. The conventional cardiac navigation systems rely on invasive technologies and often radiation exposure. However, VR-CARDIO uses electrical signals collected from multiple points on the patient's torso to perform non-invasive electro-anatomical mapping of the heart, aiding in the identification of arrhythmias without the risks associated with invasive procedures. Its ability to provide three-dimensional and holographic visualizations overcomes the limitations of two-dimensional visualizations, facilitating deeper analysis and a better understanding of the structure and function of the heart.

VR-CARDIO is composed of a Web page (VR-CARDIO Explore) and an application (VR-CARDIO VHET360), as described below in 6.1 and 6.2

6.1 VR-CARDIO Explore

VR-CARDIO Explore is a Web page that manages raw data, storing it, launching the algorithms to process it, and uploading it to the database to be able to access it through the VR-CARDIO VHET360 desktop application. On this website, data from recorded sessions with an external acquisition system such as patient data or electrode signals can be seen.



Figure 1. VR-CARDIO Explore logo.

6.2 VR-CARDIO VHET360

VR-CARDIO VHET360 is a visualization software which contains a series of tools for the visualization and management of cardiac electrical data, collected with an external system. This application is connected via an API to the database where VR-CARDIO Explore stores the processed data. This software has different ways of visualizing the data; 2D display, VR glasses and holographic display, all in an online room to interact with other users.

7. Use of VR-CARDIO

7.1 Previous information

7.1.1 General safety and operational requirements

To ensure the correct and safe operation of the software and to avoid serious personal injury or damage to property, it is recommended to read the user's instructions for use in its entirety and to

pay special attention to this section before using the software. The user must observe detailed safety precautions to avoid risks during the use of the software.

7.1.2 Potential device benefits

Current diagnosis of arrhythmias through electro-anatomical mapping generally requires invasive electrophysiological study using catheterization and cardiac navigators.

7.1.3 Additional considerations

- Procedure for reporting adverse events: for any problems or inquiries that may arise, it is recommended that users directly contact the Spika Tech support team. This can be done by sending an email detailing the situation to the following contact email: contact@spikatech.com.
- Possibility of follow-up: the use of this software does not require additional visits or follow-up. Should there be a need to review an existing case later, it can be done through VR-CARDIO Explore and VR-CARDIO-VHET360-Visualization using the automatically generated Session ID or Patient ID.

7.2 VR-CARDIO Explore

7.2.1 Language selection

There are three official languages available for VR-CARDIO Explore: Spanish, English and Arabic. You can select your preferred language using the menu located in the top left corner.

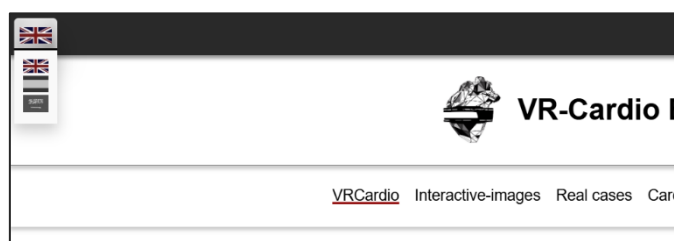


Figure 2 VR-CARDIO Explore language selection.

7.2.2 Registration



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

To access the profile section, the user must complete a registration process with the required personal data on the platform. This step is done by accessing the registration page, accessible through the [link](#)

(<https://VR-CARDIOexplore.com/#/signup>). In this page clicking on the person icon at the top right and filling in the fields with the corresponding information.

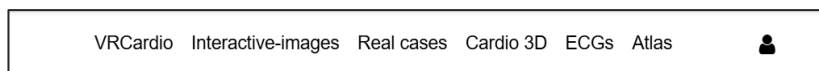


Figure 3. Logging page access clicking on the person icon.

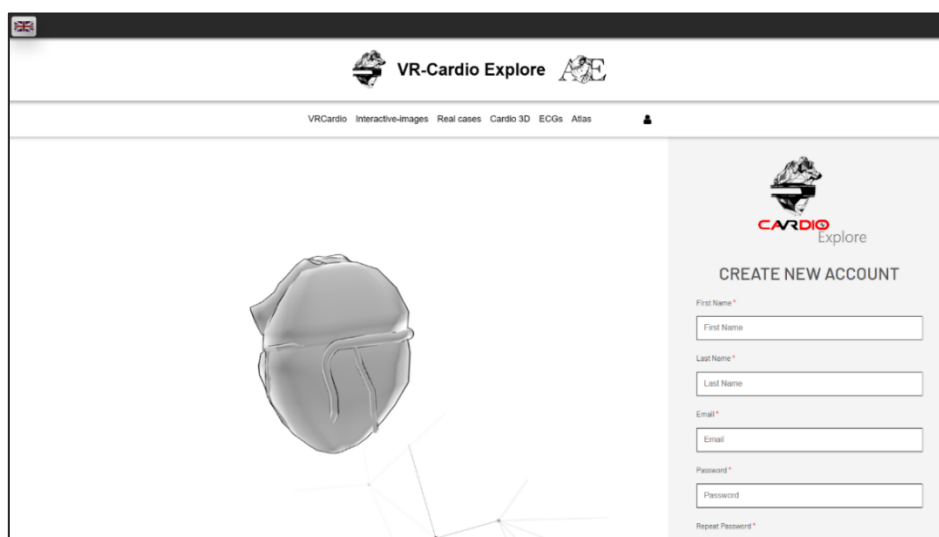


Figure 4. Registration page interface for VR-CARDIO Explore.

7.2.3 User login



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

Once the user has registered, the login can be done, using his/her credentials on the corresponding page (<https://VR-CARDIOexplore.com/#/login>).

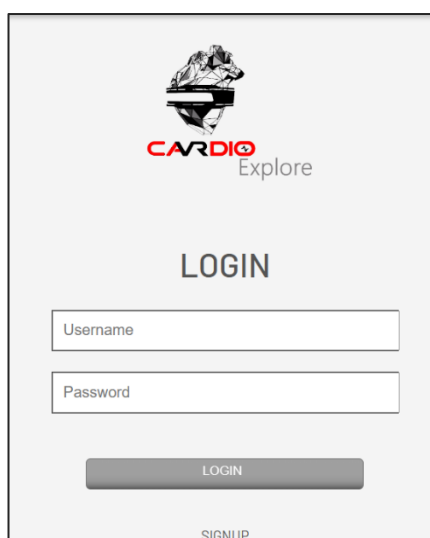


Figure 5. Login page interface of VR-CARDIO Explore.

7.2.3 User password recovery

If the user wishes to access the personal area but faces difficulties in accessing the profile due to credential problems, he/she can go to the password recovery page (<https://VR-CARDIOexplore.com/#/resetpassword>).

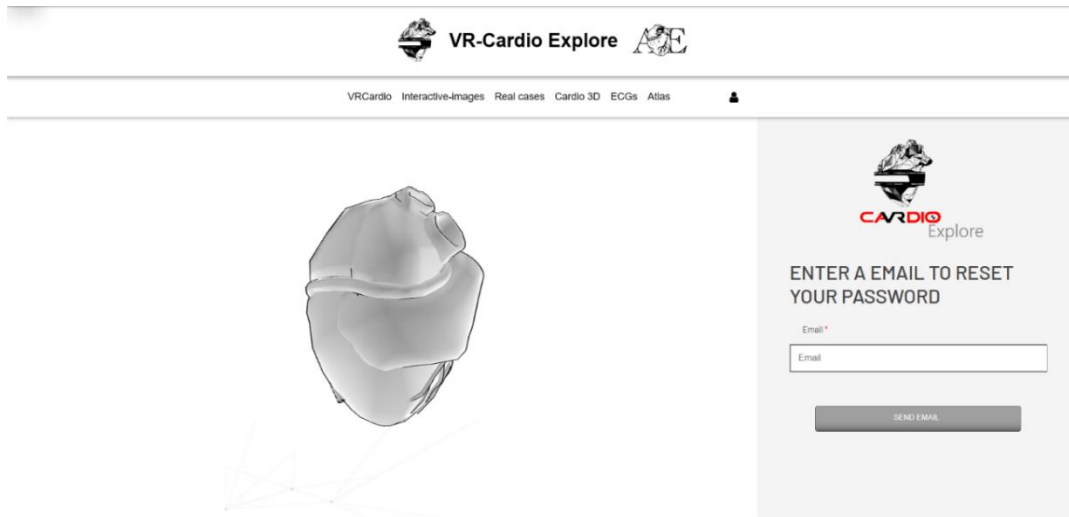


Figure 6. User password recovery page.

In this space, the e-mail address associated with the inaccessible account must be provided. A temporary access code will then be sent to this address, enabling the creation of a new password.

7.2.4 Patient registration



WARNING: Incorrect patient registration or data collection may lead to inaccurate results.

If this is the first time processing a patient's session, registration as a new patient is mandatory. This step is essential to ensure proper information management and to provide a personalized, user-centric experience in the VR-CARDIO Explore environment. This can be done by accessing the VR-CARDIO section of the profile, which will appear on the left side of the web page after clicking again on the icon of the person mentioned above.

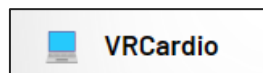


Figure 7. Access icon for VR-CARDIO section of the profile.

And enter the “Patients” section.



Figure 8. Patients section icon.

In this section, it is imperative to go to the "Add Patient" area, located at the top left of the screen.

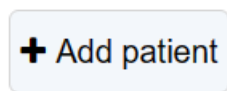


Figure 9. The "Add patient" icon permits to create a new patient profile.

Here, all the fields necessary for the creation of the patient profile should be completed, ensuring that the relevant information is captured comprehensively and accurately. This step facilitates the organization and tracking of cardiac data associated with each patient in VR-CARDIO Explore, contributing to efficient and personalized management of clinical information.

Add patient

Return

Name: *

Name

Surname: *

Surname

Age: *

dd / mm / aaaa

Sex: *

Other

Height (cm): *

Height

Weight (kg): *

Weight

Body type: *

Endomorph

Abdominal diameter (cm):

Abdominal diameter

Pectoral diameter (cm):

Pectoral diameter

Physical state: *

Normal

Figure 10. Patient information fields. The fields marked as mandatory must be filled out.

7.2.5 Session processing



WARNING: Loss of internet connection may result in data loss

To start processing a session, it is necessary to have an existing user account. If this is the case, go to the Sessions section.



Figure 11. Sessions section icon

In this section, it is essential to go to the "Add Session" area, located at the top centre of the screen.

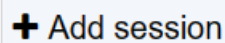


Figure 12. "Add session" icon. This icon opens different informative fields.

Here, all the fields necessary for the creation of the session must be completed. In Session type option, select the type of external data source (ECG or Personalized external data recording system). The fields marked as mandatory must be filled in. "User" corresponds with the patient who registered for this session, "ECG type" corresponds with the ECG file format and "ECG" where the ECG file must be added.

Session type

Ecg

User *

Notes

Notes

Previous pathologies

Previous pathologies

Previous treatments

Previous treatments

Ecg type

Normal

ECG *

Add ECG

SAVE

Figure 13. Informative fields. The fields marked as mandatory must be filled out.

After completing all signals processing, a global display of the signals can be achieved by accessing the viewing section (graphic symbol) of the new session in VR-CARDIO Explore. However, for more detailed and complete information, it is essential to access the VR-CARDIO VHET360 visualization tool.

Name	Creation date					
	2/8/2024, 9:15:55					

Figure 14. Selecting patient whose signals are to be displayed.

7.3 VR-CARDIO VHET 360

7.3.1 Installation

The file VR-CARDIO-VHET360-Visualization-v1.0.0.zip is available for download from VR-CARDIO website or may be provided by Spika Tech in a pen drive. To start using VR-CARDIO VHET360, unzip the file, open the VR-CARDIO-VHET360-Visualization-v1.0.0 folder and run the VR-CARDIO-VHET360-Visualization.exe. file.Unity provides two main rendering pipelines: HDRP (High-Definition Render Pipeline) for high-fidelity graphics on powerful platforms and URP (Universal Render Pipeline) to ensure performance and compatibility with a wider range of devices, including mobile. HDRP offers superior visual quality with advanced features such as physical lighting and complex effects but requires powerful hardware. URP, on the other hand, is more versatile and enables higher performance, although it may lack some of the advanced graphical details offered by HDRP.

7.3.2 Languages

VR-CARDIO VHET360 is available exclusively in English.

7.3.3 Login screen



WARNING: Credentials are unique and private. They should not be shared with any third party to prevent any privacy breach of the collected data.

Once the application is launched, the credentials required to access the account will be entered. These credentials are the same as those previously entered on the VR-CARDIO Explore website. On the footer, the corresponding medical device and CE label are displayed.

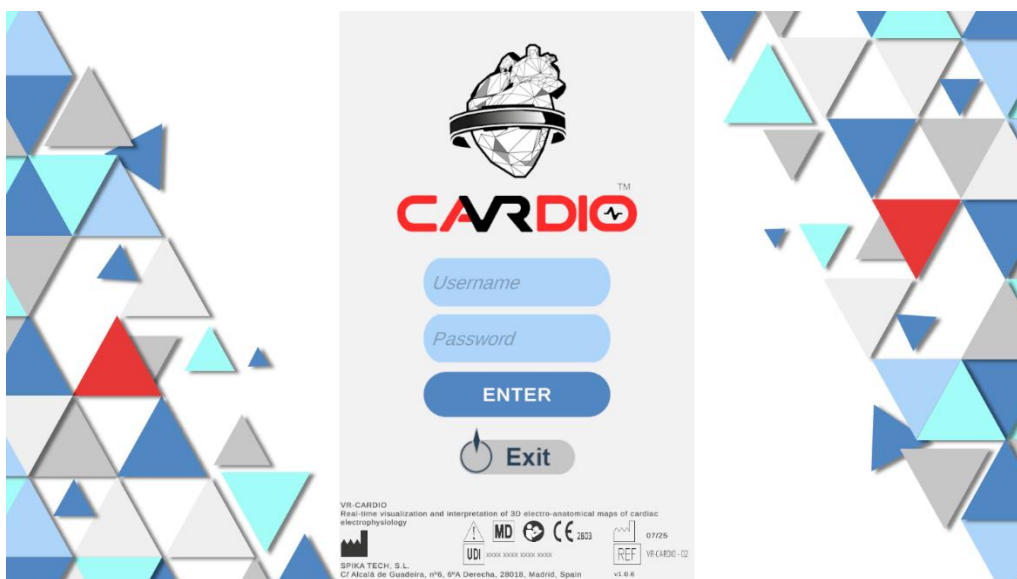


Figure 15. VR-CARDIO app Login Screen.

7.3.4 Home screen

After logging in, we access the home screen, which is the main page of VR-CARDIO-VHET360. The application has a Graphical User Interface (GUI) that is designed to be easy to use and allow the user to access the main functionalities of the application. This home screen contains four main buttons, each with a specific function.

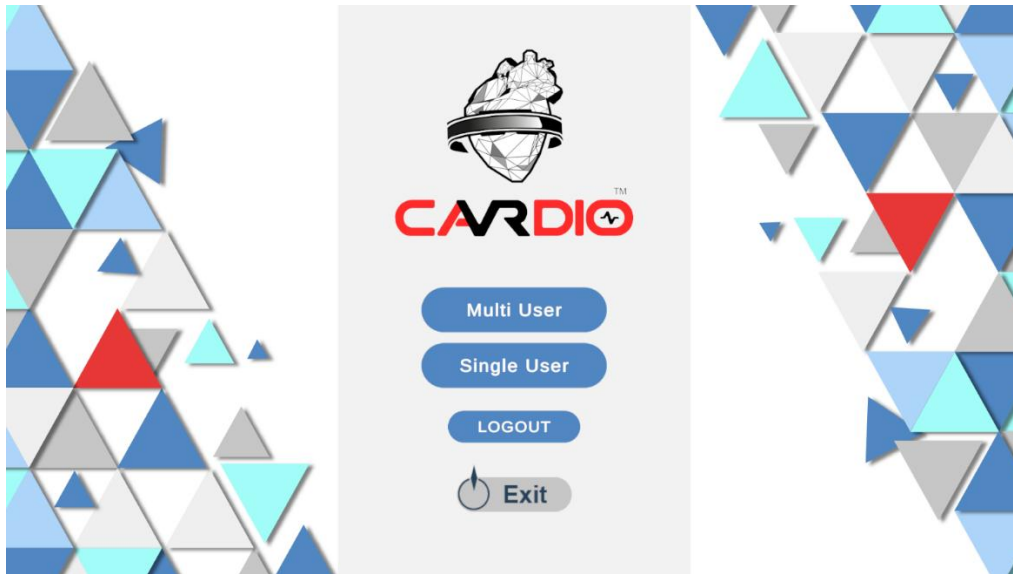


Figure 16. VR-CARDIO app Multi User/Single User home page.

The first button encountered is the "Multi User" button, which allows the user to network with other users of the application and share patient case information. Clicking this button initiates a connection to the application server that allows the user to share information with other users in real time.



WARNING: The medical professional who creates a virtual room is responsible for the individuals with whom the room joining code is shared, since personal data will be shared with third parties

The second button is the "Single User" button, where the user can access all the functionalities of the application, although he/she will not be able to share information with other users in real time. we'll continue with the "Single User" mode. The third button is the "Logout" button, that allows you to log out of your account and go to the previous screen.

Finally, the fourth button is the "Exit" button, which is used to close the application completely. Pressing this button closes the connection with the server, saves the changes made and closes the application securely.

7.3.5 Single User mode

The "Single User" mode is a useful feature for those users who need to work with the application without connecting with other users. By selecting this mode, the single user screen is displayed, which allows to access the application without the need of creating an online room.



Figure 17. Single User home page.



WARNING: The user is responsible for the directory where the downloaded cases are set, as it could cause a security problem.

If the user has a virtual reality system, the "VR Mode" button must be selected. Likewise, if the user has a holographic display and wishes to use it, the "Hologram Mode" button should be pressed. However, for the scope of this guide, it will not be necessary since the data will be visualized on the computer screen.

Finally, once the necessary configurations have been made, press the "Start" button to enter the application in "Single User" mode.

Upon entering the application, the user will encounter an interface that presents a series of panels organized by default. The panels allow the user to access the application's functionalities, such as loading cases, viewing graphs... To access the cloud panel and load the cases stored there, the user must go to the 3 buttons in the upper right corner of the screen. From top to bottom, the first one is for exit the application. The second one, identified as a folder icon, is the cloud button, which allows the user to load the cases stored in the cloud.



Figure 18. "Cloud button" Icon.

When the Cloud button is clicked on the main screen of the application, a panel opens showing the cases available in the Cloud. The third one is the Panel and Workspace button, that allows the user to move, hide and display panels, as well as load and modify workspaces as desired (A workspace is a specific colocation of the panels).



Figure 19. Cloud panel

When selecting the button that displays the cases, a list of all available cases will appear. Each item in the list is a file card with the information of a case:

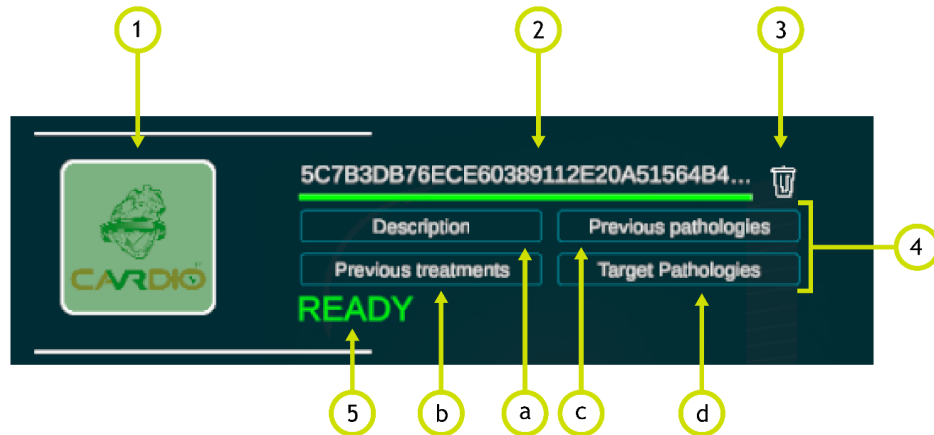


Figure 20. User information of each session.

1. **Case icon:** icon that loads the case, this icon has three stages. One stage is when the icon has a white filter, indicates that this case is not downloaded. The second stage is when the icon has a green stage, indicates that this case is downloaded and can be shown in the application. The third stage is when the icon has no filter, this indicates that the case is shown in the application.
2. **Case name:** the name under which the case has been saved.
3. **Download/Delete button:** this button is used to download a case from the cloud or delete a case locally. The icon changes depending on the status. During the download of a case, a progress bar is displayed along with the percentage downloaded, and when the download is complete, the word "Complete" is displayed to indicate completion.
4. **Information area:** in this section there are 4 buttons that display specific information from the patient when pointing it:
 - a. **Description:** general description of the case.
 - b. **Previous pathologies:** information about previous pathologies the patient has had.
 - c. **Previous treatments:** information on previous treatment the patient has had.
 - d. **Target pathologies:** information about the specific pathologies or medical conditions that are the focus of the current treatment or diagnosis.
5. **Ready information:** just additional information that shows when a case is ready for display in the application.

The next Figure shows an image of the application screen when loading one of the cases.

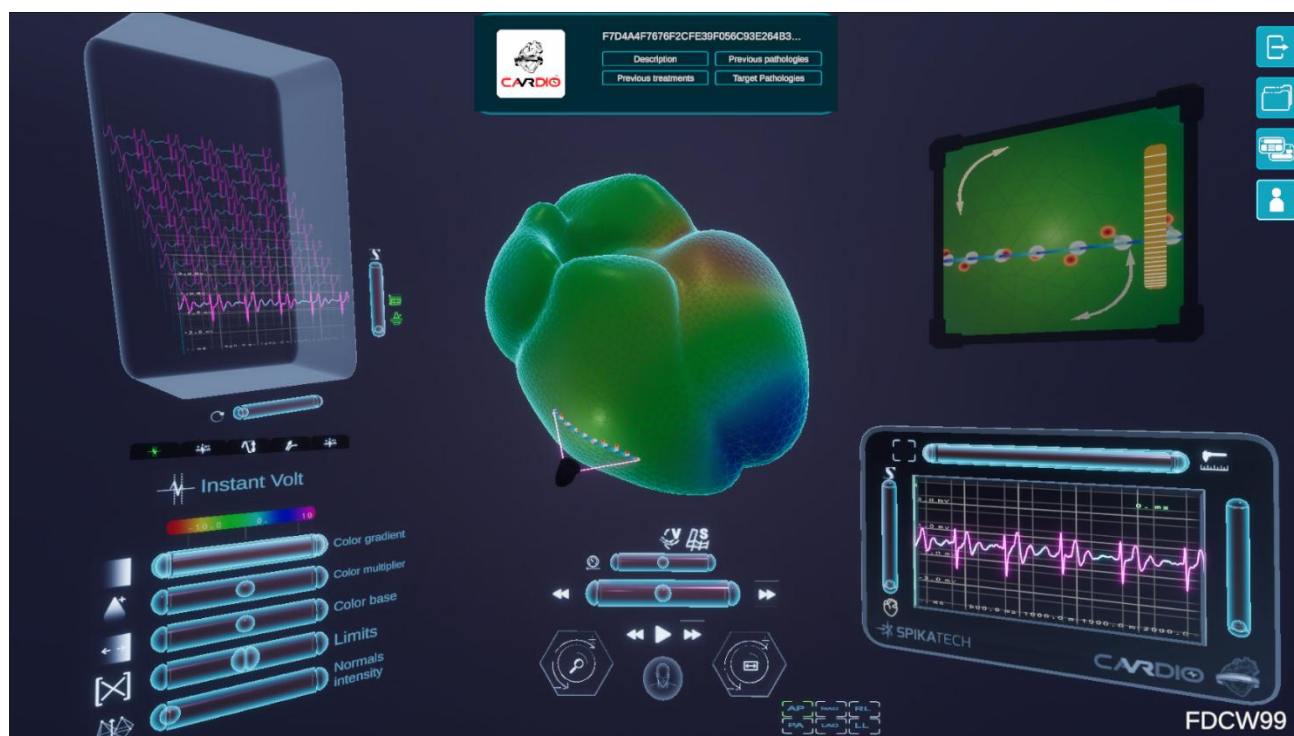


Figure 18. VR-CARDIO visualization scene.

In addition to the reconstruction of the cardiac surface, on which the different maps will be represented, there are six main interaction panels, which will be detailed below.

7.3.5.1 Display range selector panel



WARNING: The presented maps and heart reconstructions serve as diagnostic support tools and should not be interpreted in isolation. They do not replace the medical judgement of trained professionals in any case.

All the parameters that control the representation of the voltage on the cavity surface can be modified thanks to the Display Range Selector Panel, as well as the selection of the different provided maps, both the temporal map and the static maps.

In descending order, the first thing to be discovered are the selection buttons for the different electrical signal display maps, described below.

- 1.- The first of these is the instantaneous voltage map. This map provides a cardiac potential representation through the potentials registered on the torso. The method consists in processing these torso signals on the cardiac mesh using a relationship matrix based on the distances between heart and torso nodes, plus convergence techniques for further accuracy.

However, it is important to note that this estimation introduces some uncertainty, and associated errors may arise. The result of this visualization is presented in the form of a dynamic map on a three-dimensional grid, which allows access to any time instant of the signals and to observe their representation on the surface. This innovative way of visualizing cardiac potentials has several uses, including the improvement of future signal processing algorithms and applications in the educational field, as it shows the complete signals instead of summaries as in other maps, although it may have a higher level of noise.

2.- The second of the maps is the propagation or isochrones map. This map provides a temporal visualization and reconstruction of the classical Local Activation Time (LAT) map, illustrating how the electrical impulse propagates across the heart's cavities. By focusing on local activation times, it highlights the precise moments when the impulse reaches specific areas, stimulating the corresponding tissue. This Map is particularly effective in identifying the flow of propagation, including acceleration, deceleration, or avoidance of certain areas. This is critical not only for pinpointing high-activity and low-activity regions (e.g., areas with altered propagation speeds or impulse avoidance indicative of damaged tissue) but also for offering a global perspective on the heart's functional behaviour.

3.- The third is the max voltage map. This map represents the distribution of maximum amplitudes across all cardiac cavities, providing a means to identify areas of maximum energy accumulation. It is a valuable tool for detecting high-activity regions potentially associated with electrical heart remodeling, as well as low-activity regions that may indicate tissue damage.

The cardiac map called as Low voltage areas map extends the functionality of the Max Voltage Map by applying a thresholding process to specifically identify damaged areas. The threshold is guided by medical expertise, typically set at 0.5 mV of recorded real potentials, a commonly used criterion for distinguishing such regions.

4.- The fourth map is the max slope map. This map highlights the maximum slope observed across the signals, which is closely linked to regions of maximum energy accumulation. While it shares similarities with the Max Voltage Map in terms of the insights it provides, its added value lies in its correlation with action potential amplitudes. This relationship is well-established in the field, making the map particularly useful for analyzing extra potential signals.

5.- The fifth map is the cardio polar map. Cardio polar is an advanced three-dimensional visualization tool designed to enable electrophysiologists to analyze the dynamics of depolarization and repolarization of the heart in real time. This system facilitates the observation of the cardiac polarization front through a simplified representation of electrical potential signals, focusing on temporal and spatial aspects.

6.-The sixth map corresponds to the classical *Local Activation Time* (LAT) map. It is a static representation that records the activation time of different regions on the surface of the cardiac tissue during each cardiac cycle. Specifically, it captures the moment when each region undergoes depolarization. This process reflects how the electrical activation propagates across the tissue, as neighboring regions depolarize in succession, triggering one another. The LAT map serves as the temporal reference for reconstructing the depolarization

wave in the *propagation map*, where a wavefront is estimated and animated according to the activation times recorded in the LAT map.

Below are shown both the icon and the descriptive text of the currently selected map. Continuing down the horizontal bar of colour gradients can be seen, which indicates which colours correspond to which voltages in the cavity. In the figure, values of voltages below -1.5 mV would correspond to orange and reddish colours, values around 0 mV would fit greenish and light blue colours and values above 1.5 mV would fit dark blue and purple colours.

On the left of this horizontal bar, a circular arrow icon button can be observed, and can be used to reset all the panel parameters to their default values. On the right, the button represented with the icon of an eye can be found, which is explained in the Workspace Storage Panel.

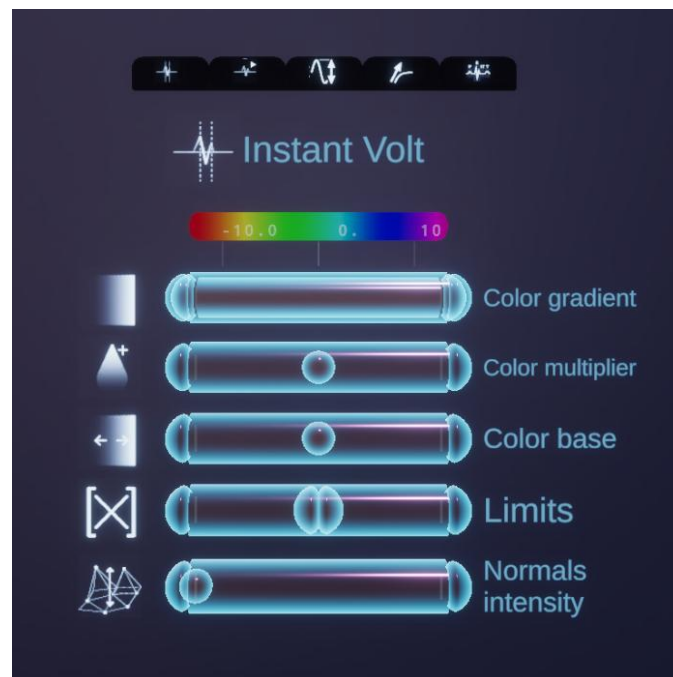


Figure 19. Colour panel.

Below the previous horizontal bar, the colour gradient control slider can be appreciated. Dragging the left end to the right will trim the colour gradient and, as it can be seen in the figure below, in which the reddish colours have been trimmed. This allows its customization to cater to the user's needs. Dragging the right end to the left will do the same for the blue and purple colours. The button to the left of the slider, represented with a gradient, is the reset button to the default values of the slider, it will only reset the value of the slider to its right.

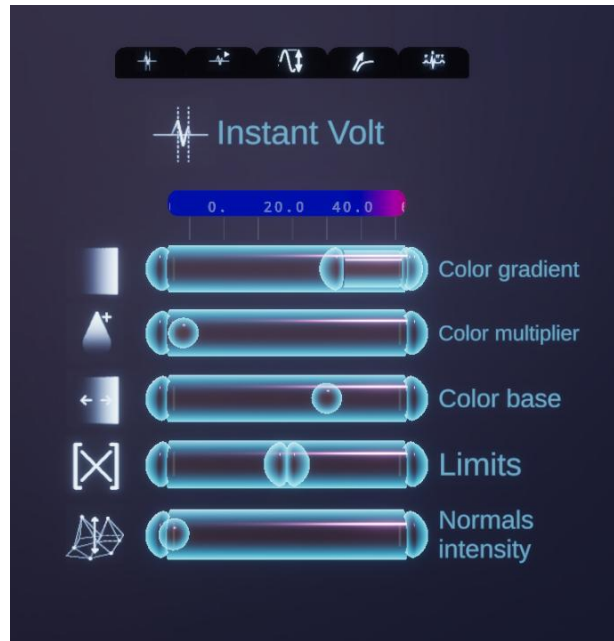


Figure 20. Colour panel sliders customizing.

Moving on to the next slider, there is the colour range multiplier that increases the voltage range, that is, dragging the centre handle to the left will increase the minimum and maximum numerical ranges of voltages. Dragging the handle to the right will do the same by decreasing the range. The button represented by a drop to the left of the slider will reset to the default value.

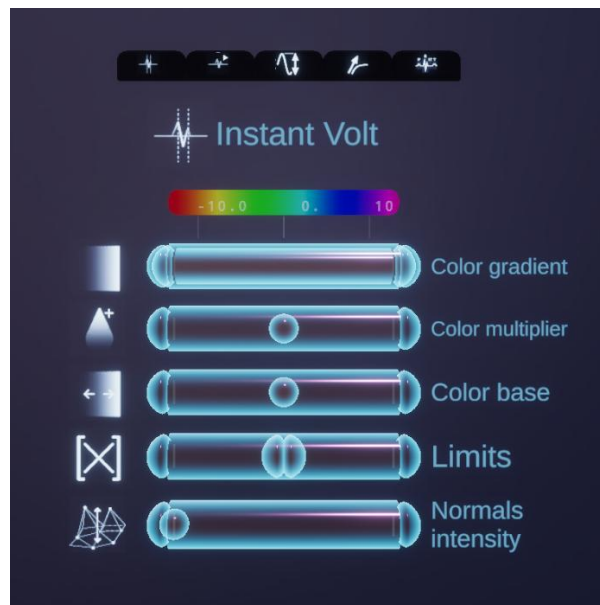


Figure 21. Colour panel sliders final mode.

The next slider, the base colour shift, allows for adjustment of the voltage ranges mapped to the gradient. Shifting the slider to the left causes the numerical ranges to move to the left, while shifting it to the right moves them to the right. This enables precise selection of the voltage ranges that correspond to the colour gradient. The button to the left of the slider, represented with a

gradient and two arrows pointing outward, will have the reset button to the default value of the slider itself.

Continuing with the next slider, the colour gradient transparency limits controller is presented, with it, a zone in which those voltages corresponding to the inside of this zone are completely transparent can be seen, providing a better view of what is happening in the back of the cavity.

This transparency zone is reflected both in the horizontal colour gradient bar and in the Main Signal Panel, where a green rectangle indicates that the voltages inside it will be completely transparent is displayed.

The button to the left of the slider represented by an "X" resets the slider to its default values.

Finally, the slider for managing the intensity of the heartbeat movement is displayed. Dragging the central controller to the left reduces the intensity, until the movement is cancelled, and dragging it to the right increases the intensity.

The button on the left closest to the slider represented with a double arrow pointing up and down, is the button to reset the intensity of the heartbeat movement to their default value.

7.3.5.2 Main signal panel

This panel is designed for in-depth manipulation of a selected signal, offering users precise control over various aspects of signal visualization and interaction. It features multiple controllers and tools to enhance the user experience.

At the top of the panel, there are two buttons and a horizontal slider. The first button resets the horizontal zoom (x-axis) of the signal, allowing users to quickly revert to the original view. The second button, positioned on the right, enables a measurement tool that lets users interact directly with the signal display for detailed analysis. The horizontal slider below these buttons allows users to zoom in or out along the x-axis, providing finer control over the signal's timeline.

On the left side, there is a vertical slider and four buttons. The vertical slider enables users to select a specific signal from the Surface Electrogram Panel, displaying it within this detailed view panel. The four buttons represent different sections of the heart: the overall heart, atria, and ventricles. Pressing any of these buttons masks or unmask the corresponding cardiac cavity, helping users focus on specific heart regions during signal analysis.

On the right side of the panel, a vertical slider allows users to adjust the zoom on the y-axis, making it possible to amplify or minimize the signal amplitude for easier examination of variations.

Additionally, users can click and drag on the signal display window to navigate through time, offering seamless interaction with different sections of the signal for more comprehensive temporal analysis. This combination of features ensures users can efficiently manipulate and interpret the selected signal with precision.



Figure 22. Main signal panel.

7.3.5.3 Time panel

This panel is the focus for most of the interactions related to time management. Although there are a couple of interactions that are not directly related, they do have an indirect connection to this main function.

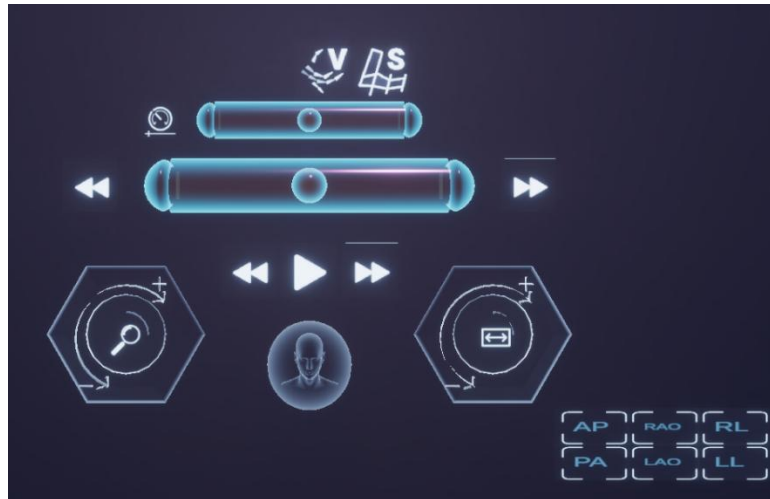


Figure 23. Time panel.

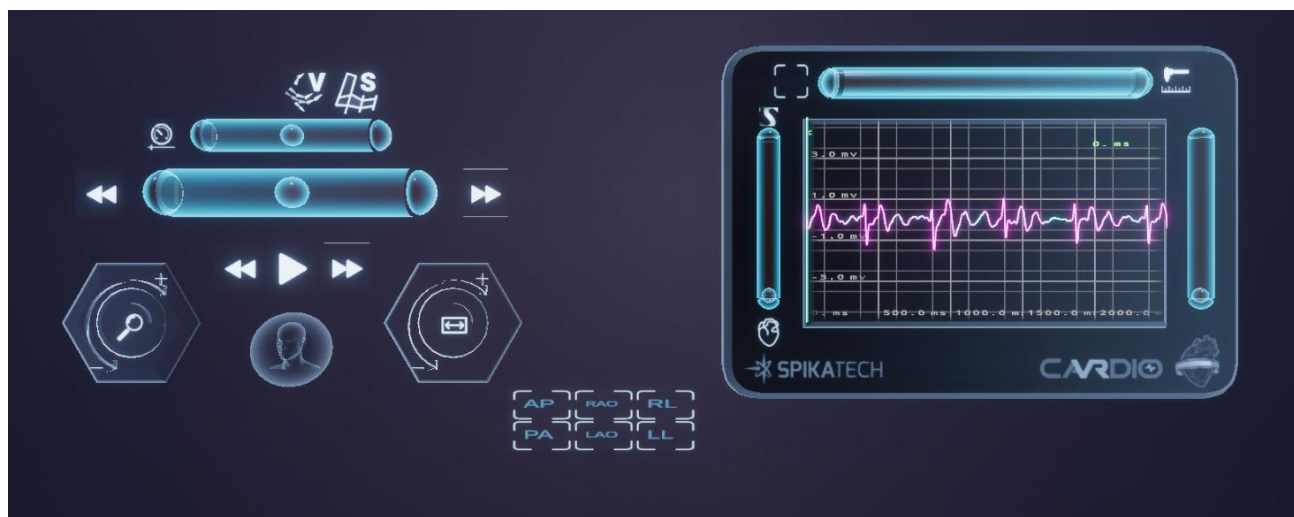


Figure 24. Time panel with main signal panel.

Just below the buttons mentioned above, there is the first slider that allows adjusting the autoplay speed. Dragging the slider to the left slows down the playback, while moving it to the right speeds it up.

The next slider, located immediately below, controls manual time playback. Dragging this slider to the left moves it backward in time and moving it to the right moves it forward. The speed of moving backward or forward in time increases as moving further to the extremes. Next, there are three buttons.

- The centre button, with the "Play" symbol, allows to start or stop automatic time playback. On either side of this button, there are two buttons that allow to go backward or forward in time in specific increments. Intuitively, the left button moves backward in time, while the right button moves forward.
- The two hexagonal buttons have a different interaction. To use them, click on them and make circular movements with the corresponding controller, either a mouse or a Virtual Reality controller. The left hexagon is used to zoom the time axis of the signal plots in the main panel and in the Surface Electrogram Pane. The right hexagon is used to scroll on the same time axis.

The bust at the bottom of the panel is a button and at the same time an indicator. It rotates to represent from which direction the cavity is being viewed. Pressing the button resets both its rotation and that of the cavity to its initial rest rotation.

In the virtual reality application, three different viewing modes are offered:

1. **Large view away from the observer:** in this mode, the scene is represented in an enlarged form and away from the observer, allowing a panoramic view of the cavity and its surroundings. This perspective provides a detailed overview of the structure.

2. **Mock-up mode, close to the observer:** in this mode, the representation of the cavity is shown in a smaller scale and closer to the observer. The perspective is like observing a physical model, allowing for a more accurate examination of details and a closer perception of the structure.
3. **The observer enters the cavity and can navigate inside:** this mode provides an immersive experience in which the observer can enter the cavity and explore its interior. By using navigation controls, the user can move freely inside the cavity and examine details from different perspectives.

These three virtual realities viewing modes provide varied options for interaction and detailed analysis of the cavity according to the user's needs and preferences.

7.3.5.4 Navigation camera panel

This panel oversees controlling the displacement of a projection system that simulates a camera on the surface of the cavity. This camera allows visualizing the portion of the cavity or the heart located below it and emits ten rays that interact with the surface. These rays access the closest vertices of the mesh where the electrical signal information is stored. These electrical signals are subsequently represented in M Mode Panel, providing a detailed visualization over time of the signals.

The double arrows located in the upper left corner and in the lower right corner rotate the camera in the "z" axis, allowing rotations about the viewing axis itself. To interact with this handler, press the arrows and make circles around the centre of the "navigation camera" panel.

The slider on the right side, represented by a pattern of horizontal lines, of the panel manages how close or far the camera is with respect to the cavity. Clicking and dragging upwards will move the camera away from the cavity (up to a certain limit) and dragging downwards will move the camera closer to the surface (up to a certain limit).

Finally, the button at the top right position, represented by four corners, toggles between two sizes for the panel, thus bringing the panel closer to the user and improving its visualization.

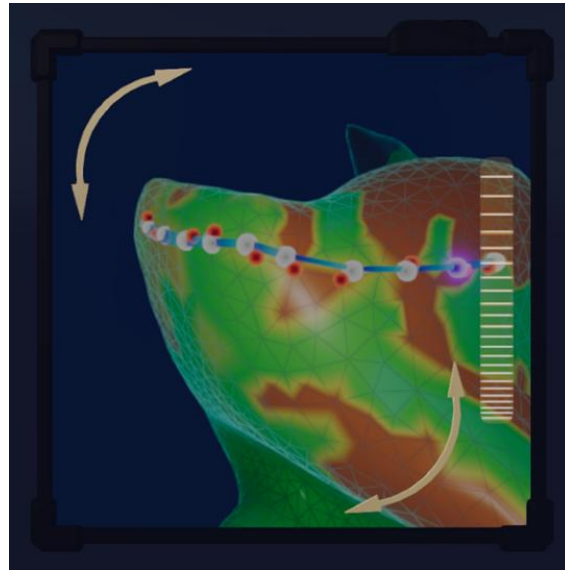


Figure 25. Navigation camera panel.

7.3.5.5 Surface electrogram panel

This panel represents the ten signals obtained by the Navigation Camera.

This panel provides a visualization along the time dimension of a series of samples ordered by the projection of a curve, adjusted to the surface. In this way, it allows the specialist to access very quickly the signals of an area of interest.

The horizontal slider regulates the contrast of the signals, dragging the central slider to the left attenuates the contrast of the signals and dragging it to the right increases it.

The vertical slider selects the signal to be displayed in the Main Signal Panel, highlighting in the Surface Electrogram Panel with a brighter colour.

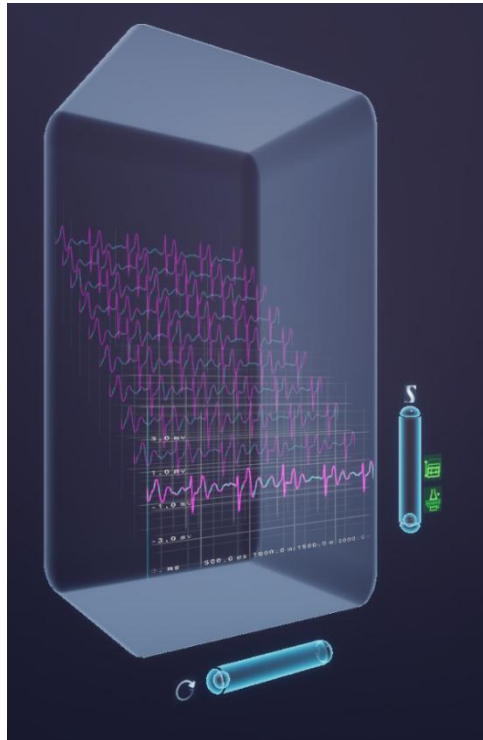


Figure 26. Surface electrogram panel.

The two buttons to the right of the previous slider provide different panel displays. With both buttons deactivated, the panel is compressed in depth and height. Pressing the upper button will expand in height, while pressing the lower button will expand in depth. With both buttons activated, it will expand in both dimensions.

These different perspectives make it easier for the specialist to compare precisely the tissue under study in spatial-temporal terms, helping to detect fragmented activation fronts, among other features.

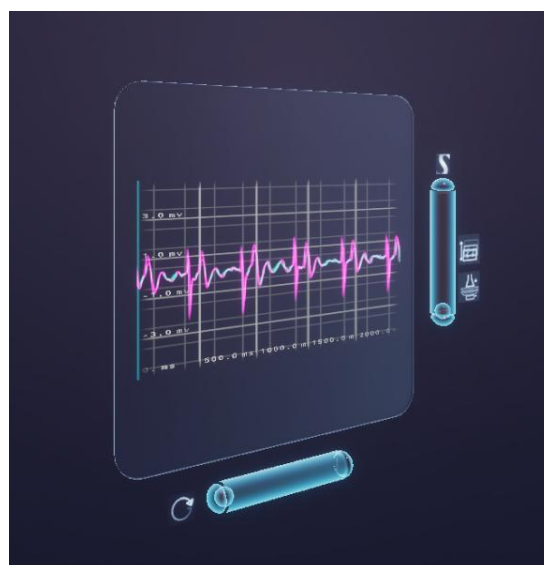


Figure 27. Surface electrogram panel compressed along Y and Z axes.

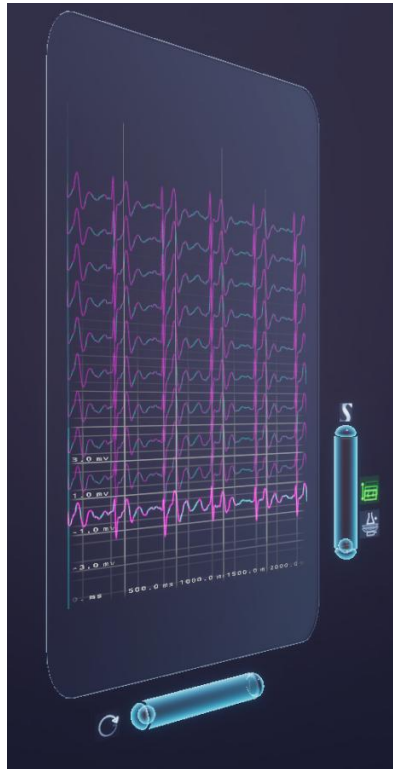


Figure 28. Surface electrogram panel compressed along Z axis.

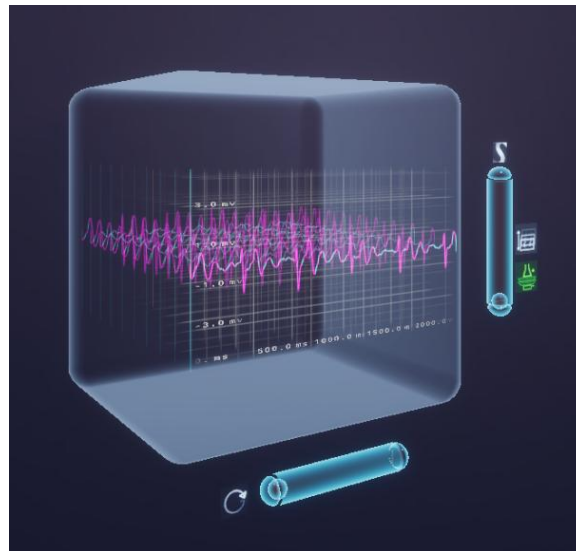


Figure 29. Surface electrogram panel compressed along Y axis.

7.3.5.6 Torso signals panel

This panel offers two distinct modes, each designed to provide a different level of interaction and visualization based on the user's needs. These modes are accessible through two dedicated buttons, allowing seamless switching between various data representations.

- **Mode 1:** The first button switches the panel to a mode that presents the ECGs. This mode shows standard ECG signals, allowing users to analyse the patient's heart activity more effectively through familiar and clinically relevant patterns.
- **Mode 2:** Torso visualization with electrode mapping by pressing the second button, the panel shifts to a 3D visual representation of the patient's torso, displaying the distribution of the electrodes on the surface. Users can interact with this mode by selecting individual electrodes, which will display the specific signal acquired from the chosen electrode. This mode is particularly useful for spatial analysis, helping users correlate specific signals with their corresponding electrode positions on the torso.

These two modes provide a flexible and intuitive interface, enabling users to switch between processed electrodes signals, and spatial electrode mapping with ease, enhancing both diagnostic precision and workflow efficiency.



Figure 30. Mode 1: ECG signals

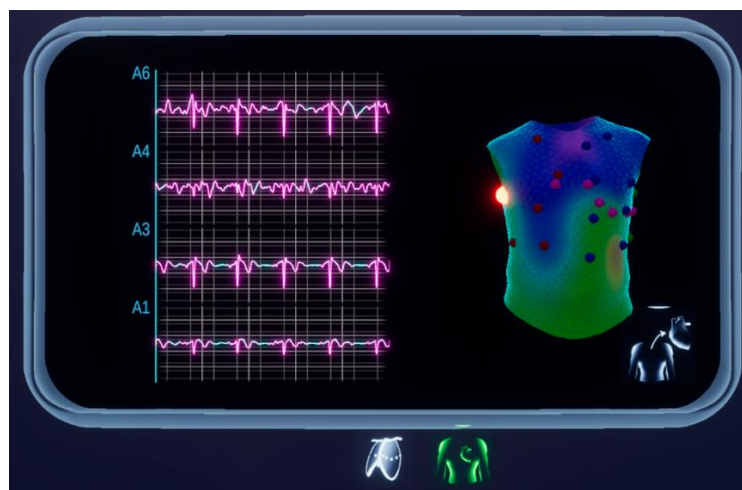


Figure 31. Mode 2: Point electrodes in torso selector

7.3.6 Multi User mode



WARNING: The medical professional who creates a virtual room is responsible for the individuals with whom the room joining code is shared, since personal data will be shared with third parties.

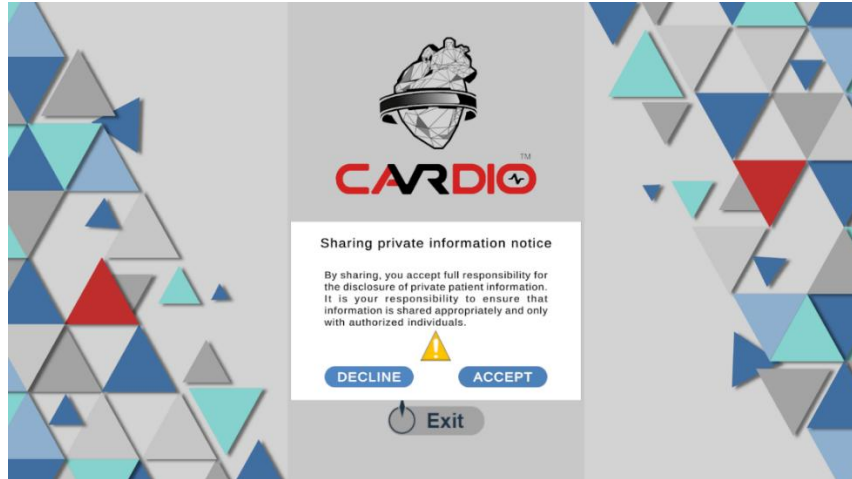


Figure 32. Data sharing acceptance.

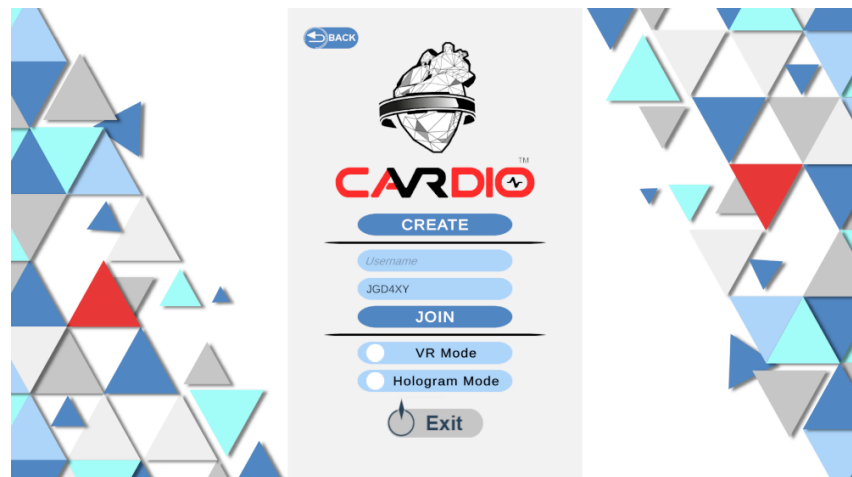


Figure 33. Multi User home page.

Selecting the "Multi User" button directs the user to the online mode screen, presenting two options: create a room or join an existing room. To create a completely new room, follow these simple steps:

- Insert a username in the "Username" space, otherwise the system will provide a default one.
- If the user has a Virtual Reality system and wants to use it, the "VR Mode" button must be selected. In the same way, if the user has a holographic screen and wants to use it, the user must press the "Hologram Mode" button.



WARNING: Virtual Reality glasses and a PC with them are required for Virtual Reality viewing.

- Once the previous steps have been completed, the "Create" button can be pressed to create the room.
- When entering the created room, in the lower right corner the room code will be provided, which must be shared through another channel, for example, e-mail, with those users willing to enter the room.

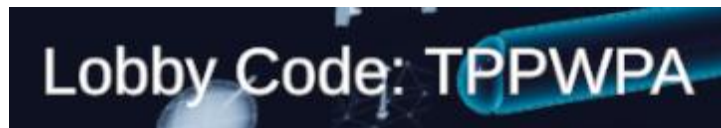


Figure 34. Example of a provided code needed to enter the room.

If entering an existing room is desired, proceed as follows:

- Insert a username in the "Username" space, otherwise the system will provide a default one.
- If the user has a Virtual Reality system and wants to use it, select the "VR Mode" button. In the same way, if the user has a holographic display and wants to use it, the user should press the "Hologram Mode" mode.



WARNING: Virtual Reality glasses and a PC with them are required for Virtual Reality viewing.

- Finally, the user will have to contact the room creator to get the room code, which the user will have to write in the "Join Code" space and press the "Join" button to enter the room.

Once inside the visualization scene, you will find practically the same scene described in the previous section. One of the differences with the "Single User" mode interface is the online user button, located below the Panel and Workspace button. When accessing the User panel, all the users present in the room can be observed. In this menu, the user hosting the room (room host) can manage the voice chat permissions of the users, allowing them to mute them or enable their microphone as needed. In addition, as the host, the virtual token that determines who holds the role of room administrator can be managed.

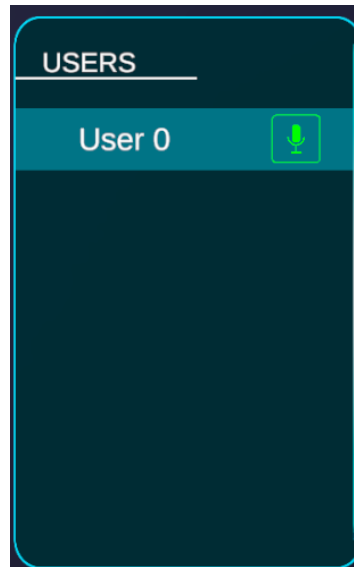


Figure 35. Users panel.

As in the other modes of the application, the "Back" and "Exit" buttons are available to return to the home screen and exit the application, respectively.

Other users are visually identified through a distinctive colour marker that indicates the direction in which they are pointing their cursor or Virtual Reality (VR) device. This system enables the detection of other user's focus on a specific panel, adjustments to room settings, or interactions with the virtual cavity. In addition, when a user communicates via voice chat, their marker lights up to identify the audio source easier for other assistants.



WARNING: A poor internet connection may influence the real-time position of the pointer of other assistants.

8. Permissions

VR-CARDIO system is designed to be used by electrophysiologists and cardiology specialists outside of operating room settings to assist in the real-time visualization and interpretation of three-dimensional, holographic, stereoscopic 360° visualization electro-anatomical maps of cardiac electrophysiology.

	Description	Access
Profession-als	This is the user designated to create new patients and sessions, visualize already computed sessions and edit any data from the already created patients. Only electrophysiologists	With this access, the user will have access to all the patients and sessions added with their profile and be able to visualize and edit specific data on them, for clinical use. (can create content and has access to advanced functionalities).

	and cardiology specialists can have this type of access.	
Admin	This is the user responsible for managing user profiles. Only web administrators, who will always be SPIKA TECH's personnel, can have access to this type of access.	With this access, the user has access to all the available tasks and ECG reports with editing and upload permissions for technical support purposes only, excluding clinical use, for every user in VR-CARDIO. This type of user can also manage the rest of user types, by managing the information, creating and deleting organizations, and changing their roles' permissions. This user profile has only administrative and management tasks, with no operation role according to the intended use of the device. For this reason, those users will be excluded from the test.

9. Troubleshooting / Residual anomalies

9.1 Insufficient connection quality

9.1.1 Inability to collect and display data

If the connection is very slow, it will not be possible to display data from the device.

9.1.2 Solution

To improve the connection, check on your PC if there is a network with better signal quality.

9.2 Insufficient data quality

9.2.1 Non-optimal data quality detection

If the signal quality is not optimal, it may be due to various factors, such as errors during the data acquisition or insufficient quality in the EP data.

9.2.2 Solution

To avoid this type of incident, it is essential to check the quality of the EP data input.

10. Maintenance and monitoring

For maintenance and monitoring of this device, please adhere to the following guidelines:

- **Functional testing:** perform functional tests on the software to ensure all systems are functioning correctly.
- **Software updates:** keep the software up to date by installing any available updates provided. Software updates may include bug fixes, performance improvements, and new features.
- **Data integrity:** verify the integrity of the data acquired.
- **User training:** provide adequate training to users on how to properly use, maintain, and monitor the software. Educate users on common troubleshooting procedures and safety precautions.
- **Record keeping:** maintain detailed records of maintenance activities, such as testing. Keep records of software usage and monitoring sessions for reference.
- Spika Tech will conduct annual service activities for the system at the customer's site during the warranty period. These activities will encompass any necessary actions identified by Spika Tech to ensure the system operates properly. Service activities will be scheduled during normal business hours or, if conducted alongside functional maintenance, may be re-scheduled.
- The disposal of VR-CARDIO is the responsibility of the user and must be carried out in accordance with local requirements.

11. Frequently Asked Questions (FAQs)

What should I do if the software is not responding?	If the device is not responding, try the following steps: Check all connections and make sure they are secure. Restart the computer. If the problem persists, contact technical support for further assistance.
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How do I contact technical support?	You can contact technical support by contact@spikatech.com. The contact information is typically provided in the user's instructions of use or on the manufacturer's website. Be prepared to provide your device's model number and a description of the issue.
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12. Manufacturer information



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Calle Alcalá de Guadaira nº6 6ª Derecha
28018, Madrid, Spain

Internet site: www.spikatech.com

Email: contact@spikatech.com



Patents

This system is covered by the following patent register: European Patent Office. No. 23 382 800.3

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